UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

Humana Inc., Plaintiff, vs. United Therapeutics Corporation, Defendant.	**Case No. _____** **COMPLAINT** **DEMAND FOR JURY TRIAL**

Humana Inc. ("Humana") brings this action against United Therapeutics Corporation ("UT") and alleges as follows:

NATURE OF THE CASE

1. UT deceptively and illegally implemented a scheme to launder kickbacks to Humana's Medicare members through one or more "independent," tax-exempt patient assistance charities. This scheme was wildly successful—every $1 that UT kicked back to Humana's members caused Humana to pay more than $18 on claims for UT's drugs.

2. Such obscene returns-on-investment reflect a cynical scheme that has become inherent to the pharmaceutical industry. UT relies on third-party payors like Humana for its profits. But UT priced its drugs such that they were cost-prohibitive for the very patients that needed them, even when the patient was insured.

3. To counteract this dynamic UT acted to remove any patient's cost sensitivity by paying for those patients' share of the costs for UT drugs. In doing so, UT

effectively built the price of paying kickbacks into the cost of its products. In essence, UT created a system to funnel kickbacks to patients that were paid for by their insurance.

4. UT is a pharmaceutical company focused on developing drugs used to treat Pulmonary Arterial Hypertension ("PAH"), a rare disease. UT has become one of the most profitable pharmaceutical companies in the world, focused almost exclusively on PAH, boasting "the second highest ratio of revenues to staff in the industry."[1] In particular, UT more than tripled its profits between 2009 and 2014, with annual revenues topping more than $1.2 billion by the end of this period. UT's drugs have annual price tags as high as $170,000.

5. Humana is a private health insurer and a leading sponsor of Medicare Advantage healthcare plans and Medicare Part D prescription drug plans. Under such plans, members are required to bear a portion of the cost of their own care—as relevant here, some fraction of the cost of UT's drugs. These cost-sharing obligations act as economic check on the use of prescription drugs by members and as an economic check on the price a pharmaceutical company can charge for its drug. Through its scheme, UT was able to eliminate these economic checks by providing kickbacks to members in the form of copayment assistance.

6. Since at least 2010, UT illegally funneled money to Humana's Medicare members in order to eliminate their cost-sharing obligations. This money took the form of

[1] United Therapeutics Corporation, Annual Report, (Dec. 31, 2014), *accessible at* https://s1.q4cdn.com/284080987/files/doc_financials/2014/ar/2014-Annual-Report.pdf; United Therapeutics Corporation, Annual Report, p. 26 (Dec. 31, 2010), *accessible at* https://s1.q4cdn.com/284080987/files/doc_financials/2010/ar/2010-Annual-Report.pdf.

donations to seemingly independent, tax-exempt patient assistance charities, primarily the Caring Voice Coalition ("CVC").

7. CVC's independence from UT was in fact illusory, as CVC provided UT with information necessary to correlate its donations with its sales in direct contravention of federal law.

8. UT's scheme was eventually uncovered and, on or about December 20, 2017, UT agreed to pay the federal government $210 million to settle allegations that it submitted claims tainted by illegal kickbacks to Medicare in violation of the False Claims Act and the federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b. UT further agreed to enter into a five-year corporate integrity agreement, pursuant to which it promised to change many of its unlawful practices. The announcement of the settlement finally exposed UT's unlawful scheme to public scrutiny.

9. The DOJ alleged[2] that UT "used a third party to do exactly what it knew it could not lawfully do itself" and that "UT's payments to the [CVC] were not charity for PAH patients generally, but rather were a way to funnel money to patients taking UT drugs." This conduct violated the federal Anti-Kickback Statute and False Claims Act, which combat "schemes like [UT's] that leave Medicare holding the bag for the costs of expensive drugs."

[2] Department of Justice, Drug Maker United Therapeutics Agrees to Pay $210 Million to Resolve False Claims Act Liability for Paying Kickbacks, Dec. 20, 2017, *accessible at* https://www.justice.gov/opa/pr/drug-maker-united-therapeutics-agrees-pay-210-million-resolve-false-claims-act-liability.

10. Since 2010, Humana's Medicare plans have paid hundreds of millions of dollars to cover the costs of claims for UT's PAH drugs. Based on Humana's own investigation, many (if not the majority) of these claims were tainted by UT's unlawful scheme.

PARTIES

11. Plaintiff Humana Inc. is a corporation incorporated in the State of Delaware and headquartered in the State of Kentucky that sponsors, insures and administers health plans, including Medicare Part C healthcare plans (also commonly known as Medicare Advantage plans) and Medicare Part D prescription drug plans.

12. Defendant United Therapeutics Corporation is a pharmaceutical company incorporated in the State of Delaware and with a principal place of business at 1040 Spring Street, Silver Spring, Maryland.

JURISDICTION AND VENUE

13. The Court has subject matter jurisdiction over this action under 28 U.S.C. § 1331 because it arises under the Constitution, laws, or treaties of the United States. Specifically, Humana asserts claims arising under the Racketeer Influenced and Corrupt Organizations Act (RICO), 18 U.S.C. § 1962, *et seq*. Humana's state and common law claims are subject to supplemental jurisdiction under 28 U.S.C. § 1367, as those claims are so related to the federal claims that they form part of the same case or controversy.

14. The Court may assert personal jurisdiction over UT because UT maintains its principal place of business in Silver Spring, Maryland, and committed and / or coordinated the unlawful acts at issue within this jurisdiction.

15. Venue is proper in this district under 28 U.S.C. § 1391 because a substantial part of the events giving rise to the claims in this action have occurred in this district as it is UT's principal place of business.

FACTUAL BACKGROUND

PAH Drugs Manufactured by UT and Others

16. PAH is a rare, life threatening heart and lung condition characterized by abnormally high blood pressure that afflicts fifteen to fifty people per million in the United States.

17. UT markets several drugs used to treat PAH, including Remodulin, Adcirca, Tyvaso, and Orenitram. With the exception of Adcirca, all of UT's PAH drugs use the compound Treprostinil and are distinguishable by their means of administration (e.g. injection, inhalation, and oral administration).

18. Treprostinil mimics prostacyclin, a lipid that inhibits platelet activation—one of the initial steps in blood clotting and inflammation that can cause arterial blockage. It thereby keeps blood vessels in the lungs open and facilitates physical activity.

19. In 1997, UT paid $25,000 for the intellectual property rights to a Treprostinil-related drug that was "on the shelf" of another pharmaceutical company.[3] UT went on to sell that drug as Remodulin.

[3] 2010 Annual Report, *Supra* note 1 at 29.

20. Remodulin was UT's first PAH drug, approved by FDA in 2002. The typical dosage and frequency of Remodulin varies by means of administration; it can be delivered intravenously or subcutaneously. The annualized cost of Remodulin treatment is approximately $123,000, although the cost associated with some patients can reach roughly $172,000 per year. According to a 2019 study, Remodulin was one of the twenty most expensive drugs in the United States.

21. Tyvaso was approved by FDA in 2009 as an inhalable treatment for PAH. Tyvaso is typically taken in four separate, equally spaced doses per day. Its annualized cost is approximately $107,000 and was also identified as one of the twenty most expensive drugs in the United States.

22. Orenitram was approved in 2013 as an extended-release formulation of Treprostinil that can be taken orally that also minimizes certain side effects associated with the inhaled form (i.e. Tyvaso). Orenitram is usually taken two times a day. Its annualized cost is approximately $72,000.

23. Adcirca is chemically equivalent to Eli Lilly and Company's drug Cialis. Pursuant to a November 2008 License Agreement with Eli Lilly and Company, UT obtained the rights to market, promote and commercialize the active ingredient in Cialis for PAH. Adcirca was formally approved by the FDA for the treatment of PAH in 2009.

24. Adcirca is an orally administered tablet that treats PAH by relaxing and widening pulmonary blood vessels, which allows blood to flow more easily and improves exercise ability. Adcirca is typically administered in a single daily dose. Its annualized

cost is approximately $52,356 (substantially more than Eli Lilly & Company prices Cialis).

25. Sales of the above drugs make up the vast majority of UT's sales—sales to third-party payers like Humana.

26. UT's PAH drugs compete with similar PAH drugs manufactured by another pharmaceutical company, Actelion. As discussed below, Actelion employed a scheme much like UT's in order to maximize sales, leading to a $360 million settlement with the federal government. Actelion's competing PAH drugs include Ventavis, Opsumit, Tracleer, and Uptravi.

27. Remodulin and Adcirca now also face generic competitors manufactured by Sandoz, Inc. and Mylan N.V., respectively.

Humana's Medicare Plans

28. The national health insurance program in the United States known as Medicare has four parts – A, B, C, and D – through which health benefits are provided to individuals who qualify for them.

29. Part A covers inpatient hospital services, skilled nursing facility services, and some forms of home-based care. Part B covers physician services, outpatient hospital services, diagnostic services, and other medical services. Parts A and B also cover drugs delivered during medical procedures, and Part B specifically pays for drugs provided incident to treatment at a physician's office (called "clinically administered drugs"), so long as the drugs are used consistent with FDA approval or in another medically accepted manner. The federal government directly administers Parts A and B through CMS.

30. Individuals who are eligible for Part A and enrolled in Part B have the option of enrolling in Medicare Part C, otherwise known as Medicare Advantage, which is required to offer the same benefits covered by Parts A and B and may include additional benefits such as Medicare Part D prescription drug or dental benefits. CMS offers Medicare Advantage plans through private payors like Humana. Known as Medicare Advantage Organizations ("MAOs"), these payors provide Medicare Advantage plans to individuals pursuant to contracts with CMS.

31. Medicare Part D is an optional Prescription Drug Benefit plan ("PDP"); i.e., it is health plan that covers part of the costs of prescription drugs purchased by patients from pharmacies. Medicare Part D PDPs are administered only by private payors like Humana—CMS does not directly administer any PDPs. Medicare Part D enrollees must pay the private administrator of their prescription benefit plan a premium for their prescription drug benefit. CMS then pays a subsidy to the private administrator of the PDP plan based on each enrollees' health risk score, as determined by CMS.

32. Congress designed Medicare Part D with four "stages" of coverage, generally ranging from less to more comprehensive benefits. The details of these coverage stages have evolved over the years, but their general form has remained the same. Each requires enrollees to pay for a portion of their medication's cost to varying degrees. In fact, the amount that an enrollee has paid in a given plan year dictates which stage that enrollee is in. Thus, tracking what an enrollee has actually paid is an important part of the Medicare Part D benefit.

33. The initial stage is the deductible stage. The enrollee is expected to pay an initial, fixed amount of their annual health costs. Once the deductible is satisfied it triggers Humana's obligation to pay for claims, thus beginning the next stage.

34. Next is the Initial Coverage Stage, which requires enrollees to pay a certain amount for their drugs while Humana pays the remainder. The Initial Coverage Stage lasts until the enrollee spends a statutorily defined amount; for example, in 2011 the amount was $2,840.

35. Once the Initial Coverage Stage spend cap is reached, the enrollee enters the Coverage Gap Stage, known informally as the "donut hole." The Coverage Gap Stage generally involves enrollees paying a higher percentage of drug costs than the Initial Coverage Stage. Humana pays the remainder. The donut hole is a very controversial feature of Medicare Part D, and Congress has modified it many times recently to require drug manufacturers to offer discounts within the Coverage Gap Stage to alleviate the burden on enrollees.

36. The Coverage Gap Stage persists until the enrollee spends enough of their own money to reach the cap; for example, in 2011 the cap was $4,550. At this point the enrollee enters the Catastrophic Coverage Stage, where the enrollee pays 5% of their drug costs or a small, fixed copayment, whichever is less. Humana pays the remainder. Enrollees remain in the Catastrophic Coverage Stage until the end of the plan year.

37. Humana administers stand-alone Medicare Part D Prescription Drug Plans as well as Medicare Advantage plans that includes a Part D benefits as part of a comprehensive plan.

38. Remodulin and Tyvaso are typically reimbursed under Humana's Medicare Part C plans, whereas Adcirca and Orenitram are typically reimbursed under Humana's Medicare Part D plans.

39. In offering and administering such Medicare plans, Humana bears significant risks related to the cost and utilization of healthcare services and pharmaceuticals. When Humana assumes these risks, it relies in large part on the protections afforded by state and federal law prohibiting unlawful conduct within the healthcare industry, including laws prohibiting the submission of false, fraudulent, or otherwise unlawful claims to sponsors of federal healthcare programs and other payors.

40. Healthcare claims are not payable under Medicare if they do not comply with all applicable federal laws, including laws like the Anti-Kickback Statute, as discussed below.

41. Providers enrolling in Medicare must certify that they "understand that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations, and program instructions (including, but not limited to, the Federal Anti-Kickback Statute, 42 U.S.C. section 1320a-7b(b) (section 1128B(b) of the Social Security Act) and the Physician Self-Referral Law (Stark Law), 42 U.S.C. section 1395nn (section 1877 of the Social Security Act))."[4] Providers also submit claims for Medicare beneficiaries to the government and to payors like

[4] Centers for Medicare and Medicaid Services, Medicare Enrollment Application - Physicians and Non-Physician Practitioners Form 855I, (last accessed Dec. 8, 2022), *accessible at* https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/CMS-Forms-Items/CMS019477.

Humana using a standard claim form, the CMS 1500, which requires the provider to certify that each claim "complies with all Medicare and/or Medicaid laws, regulations, and program instructions for payment including but not limited to the Federal anti-kickback statute."

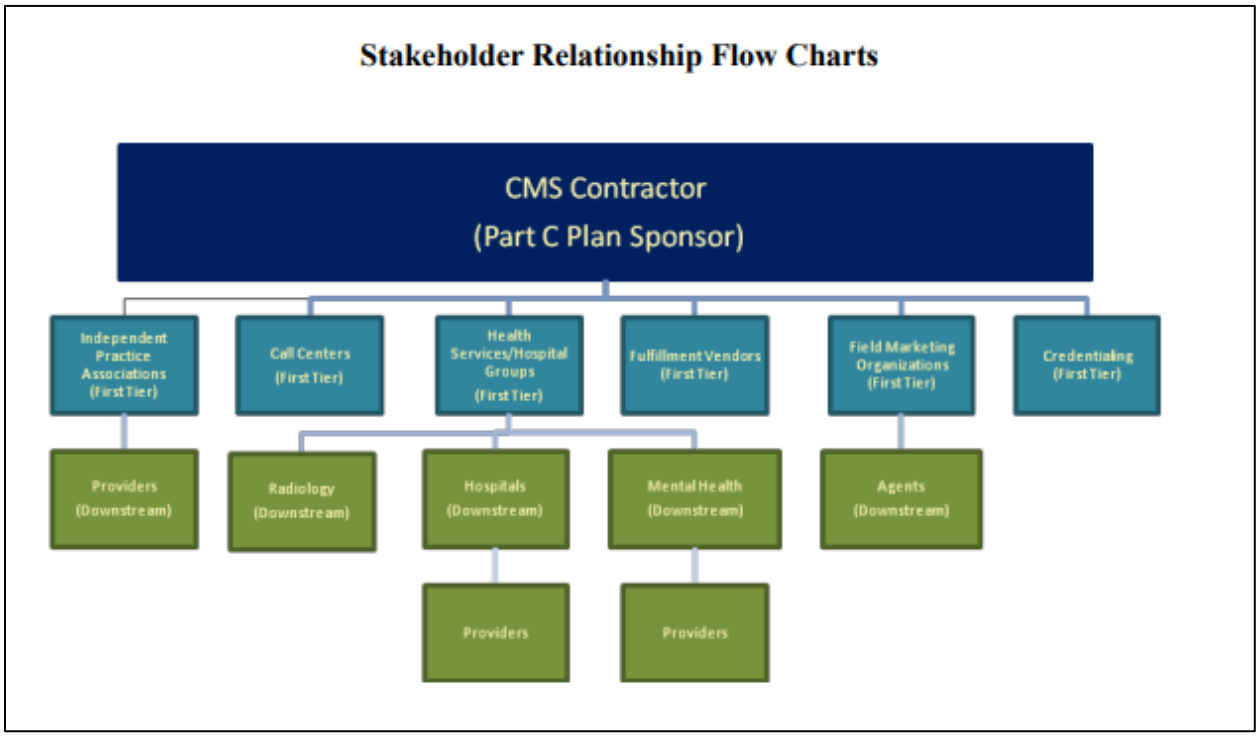
42. The CMS 1500 figures prominently with reimbursement for UT Drugs. If a patient receives a UT Drug that requires administration by a medical professional—such as intravenous Remodulin—that medical professional submits a claim to payment to Humana on a HCFA 1500 or its electronic-claim equivalent.[5]

43. MAOs and Part D plan sponsors are required to comply with "[f]ederal laws and regulations designed to prevent fraud, waste, and abuse, including, but not limited to, applicable provisions of Federal criminal law, the False Claims Act (31 U.S.C. § 3729, et seq.), and the anti-kickback statute (§ 1127B(b) of the Act)." 42 C.F.R § 422.504(h)(1), 42 C.F.R. § 423.505(h)(l). CMS holds MAOs and Part D plan sponsors ultimately responsible for complying with these requirements. *See* 42 C.F.R. § 422.504(i)(1).

44. In keeping with that requirement, MAOs and Part D plan sponsors are mandated to include conforming language in any contract with "downstream" entities. *See* 42 C.F.R. § 423.505(i). A downstream entity is any entity that enters into a contract

[5] The CMS 1500 form has been standardized into an electronic claim format known as "X12 837 Health Care Claim: Professional," or 837P. *See* National Uniform Claim Committee, 02/12 1500 Claim Form Map to the X12 Health Care Claim: Professional (837) (August 2018), *accessible at* https://www.nucc.org/images/stories/PDF/1500_claim_form_map_to_837P_v3-3_2012_02.pdf.

"below" an entity directly contracted with a MAO or Part D plan sponsor., downstream entities encapsulate contracting parties "down to the level of the ultimate provider of both health and administrative services." 42 C.F.R. § 422.500(b). As illustrated in the Medicare Managed Care Manual:[6]



45. Any contract that derives from a MAO's or Part D plan sponsor's must include language obligating the downstream to comply "with all applicable Federal laws, regulations, and CMS instructions." *See e.g.,* 42 C.F.R. § 423.505(i)(3). Thus, any entity contracted with Humana through its Medicare Advantage or Part D plans—such as providers and pharmacies that dispense UT drugs—are contractually required to observe Humana's compliance obligations.

[6] Centers for Medicare and Medicaid Services, Medicare Managed Care Manual: Chapter 21—Compliance Program Guidelines (Rev. 110, Jan. 11, 2013), *accessible at* https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/mc86c21.pdf.

46. For illustration, when a pharmacy dispenses drugs to a Humana Part D member and submits a claim to Humana, Humana is required to submit a record of the claim— called a Prescription Drug Event ("PDE")—to CMS. PDE records are essential to CMS's administration of the Part D program and are used, *inter alia*, to determine if a Part D plan is entitled to additional monthly payments to support its enrollees. PDE records thus are required to be "accurate, complete, and truthful." 42 C.F.R. § 423.505(k).

47. UT had full awareness of its need to comply with federal law. Indeed, in a 2013 contract with Humana UT represented and warranted its compliance "with all applicable federal and state laws and regulations," including the AKS.[7] UT has repeatedly advised its investors that its failure to comply with the AKS could have a material adverse effect on its business.[8]

48. UT made similar representations and warranties in contracts with its exclusive distributors such as Accredo Health Group, Inc.—an entity downstream of Humana. "UT shall be solely responsible for, and comply with, Applicable Laws," such as the AKS "governing the regulation of the . . . sale" of its products."[9]

[7] January 1, 2014 Medicare Part D Agreement between United Therapeutics Corporation and Humana Pharmacy Solutions, Inc.
[8] *See* United Therapeutics Corporation, Annual Report, p. 29 (Form 10-K) (Dec. 31, 2010); United Therapeutics Corporation, Annual Report, p. 35 (Form 10-K) (Dec. 31, 2012); United Therapeutics Corporation, Annual Report, p. 33 (Form 10-K) (Dec. 31, 2014).
[9] January 1, 2009 Specialty Pharmacy Network Agreement between Humana Health Plan, Inc. and Curascript, Inc. (now Accredo Health Group, Inc.), as amended Nov. 11, 2013.

Benefit Design and Impact of Cost-Sharing Waivers

49. Medicare plans, such as those sponsored and administered by Humana, also contain requirements that are designed to control the cost of healthcare. Specifically, such plans contain provisions requiring enrolled members to pay their cost-sharing obligations. Cost-sharing obligations can be in the form of required deductibles (amounts members must pay before the plan pays), coinsurance (amounts members must pay as a percentage of the charge for what they receive), or copays (fixed amounts).

50. These cost-sharing requirements for Federal health care programs serve an important role in protecting both the Federal health care programs and their beneficiaries by promoting: (1) prudent prescribing and purchasing choices by physicians and patients based on the true costs of drugs; and (2) price competition in the pharmaceutical market. They are intended to cause behavioral shifts in members' decisions regarding healthcare services. The intent of cost-sharing is to provide an incentive for members and their physicians to use lower-cost alternatives when possible. And if alternatives are not available, members' inability to pay cost-sharing obligations is intended to have downward pressure on the pricing of expensive drugs.

51. As a result, Medicare plans do not contemplate pharmaceutical manufacturers paying members' cost-share obligations, which would defeat their fundamental purpose.

52. Nevertheless, unwilling to lower their prices, many drug manufacturers have attempted to work around the downward pricing pressure caused by member cost-sharing obligations by either waiving those cost-sharing obligations or by paying those

cost-sharing obligations on behalf of the members. The result of these payments, which are effectively cost-sharing waivers, is that the member is not exposed to the cost of the drug, allowing manufacturers to maintain already high prices or inflate prices without having to worry about the impact of those prices on anything other than profit to the manufacturer.

53. The effect of such cost-sharing waivers on drug prices is well studied. For example, a study large study conducted in Germany in 1989 showed that when drug companies were prevented from waiving cost-sharing obligations, drug prices dropped on average between 10 and 26 percent. In other words, the drug manufacturers were able to substantially inflated prices simply by waiving required patient responsibility.

54. Researchers have also discussed the effect of drug-company sponsored patient assistance programs. Specifically in a 2009 article, researchers noted:

> Drug company–sponsored PAPs [Patient Assistance Programs] may inhibit cost-effective medication use, and their widespread use may have important implications for public drug spending. This potential impact must be better understood. Drug company–sponsored PAPs may steer patients toward and lock them into a particular manufacturer's product, even when other equally effective and less costly alternatives are available. If these patients ultimately acquire better coverage, then they may request unnecessarily expensive medications. In the case of Medicare Part D, patients' prior use of PAPs that provide subsidies for brand-name products may lead to higher overall individual and public drug spending.[10]

[10] Choudhry, Niteesh K et al., *Drug company-sponsored patient assistance programs: a viable safety net?,* Health Affairs (Project Hope), Vol. 28, No. 3 (2009), https://doi.org/10.1377/hlthaff.28.3.827.

55. Similarly, a 2014 article explained:

> Assistance programs are a triple boon for manufacturers. They increase demand, allow companies to charge higher prices, and provide public-relations benefits. Assistance programs are an especially attractive proposition for firms that sell particularly costly drugs. Faced with high out-of-pocket costs, some patients may decide against taking an expensive medication. Patient-assistance programs can convert such patients from nonusers to users. Programs must incur costs for patients who would have used the drug even in the absence of a program, but manufacturers can afford to pay a lot of $25 or $50 copayments in return for even a small increase in the sales of a $50,000 drug.[11]

56. In other words, by paying patient cost-share obligations, drug manufacturers can remove the downward price pressures on their drugs that the patients would otherwise apply, leaving payors to foot the bill of those inflated costs.

Legal Prohibitions on Pharmaceutical Companies Paying Patient Cost-Sharing

57. Federal and state law prohibits pharmaceutical companies from paying the cost-sharing obligations of their customers.

58. Medicare Parts C and D are "Federal health care programs" as defined by the federal Anti-Kickback Statute, 42 U.S.C. § 1320-7b(f), and therefore pharmaceutical companies like UT who obtain reimbursement for their drugs through any Medicare plan must comply with the Anti-Kickback Statute.

[11] David H. Howard, *Drug Companies' Patient-Assistance Programs—Helping Patients or Profits?*, New England Journal of Medicine (2014), https://doi.org/10.1056/nejmp1401658.

59. Claims that violate the federal Anti-Kickback Statute are not payable under Medicare—*i.e.*, payors like Humana that sponsor Medicare plans will not reimburse claims tainted by illegal kickbacks.

60. The federal Anti-Kickback statute makes it a criminal offense to knowingly and willfully offer, pay, solicit, or receive any remuneration to induce or reward the referral or generation of business reimbursable by any Federal healthcare program.

61. A pharmaceutical manufacturer's waiver of or payment of the cost-sharing obligations of members—either through inappropriate charitable arrangements or the use of co-payment coupons—constitutes a violation of the federal Anti-Kickback statute whether the patient at issue is enrolled in a Medicare Part A, Part B, Part C or Part D plan.

62. The federal government has issued numerous guidance documents (Bulletins) that explain what sorts of arrangements between pharmaceutical companies and charities violate the Anti-Kickback statute.

63. In 2005 OIG issued a Bulletin directed specifically to patient access programs (PAPs). Issued just before the Medicare Part D program went into effect, OIG noted that patient access programs (PAP) that were funded by pharmaceutical manufacturers and used to subsidize Part D cost-sharing amounts present heightened risks under the Anti-Kickback statute. That bulletin, as well as a 2006 OIG Advisory Opinion noted that in certain circumstances, cost-sharing subsidies provided by *bona fide*, independent charities unaffiliated with pharmaceutical manufacturers could be

appropriate, even if the charities received manufacturer contributions but only so long as certain safeguards were met.

64. Specifically, OIG noted that "[f]or purposes of an anti-kickback analysis, we would not consider a charitable foundation (or similar entity) formed, funded, or controlled by a manufacturer or any of its affiliates, to be a *bona fide*, independent charity, because interposition of the entity would not sever the nexus between patient subsidies and the manufacturer. Indeed, in most cases, the foundation would receive all of its funding from the pharmaceutical manufacturer . . .and would provide subsidies only for the manufacturer's products."

65. OIG went on to explain, "where a manufacturer PAP offers subsidies tied to the use of the manufacturer's products (often expensive drugs used by patients with chronic illnesses), the subsidies present all of the usual risks of kickbacks, including steering beneficiaries to particular drugs; increasing costs to Medicare; providing a financial advantage over competing drugs; and reducing beneficiaries' incentives to locate and use less expensive, equally effective drugs."

66. OIG also expressed concerns that the use of cost-sharing subsidies to shield beneficiaries from economic effects of drug pricing would eliminate a market safeguard against inflated prices.

67. OIG provided a blueprint for a patient-assistance program that would comply with federal law. According to OIG, all of the following should be true for such a program to be compliant:

a. The third-party administering the program is an independent, *bona fide*, charity;

b. Neither the manufacturer or any affiliate exerts any direct or indirect influence or control over the charity or program;

c. Assistance is awarded in a truly independent manner that severs any link between the manufacturer's funding and the beneficiary;

d. The charity awards assistance without regard to the beneficiary's choice of product, provider, practitioner or supplier;

e. Assistance is based on a reasonable, verifiable, and uniform measure of financial need applied in a consistent manner;

f. The manufacturer does not solicit or receive data from the charity that would facilitate the manufacturer in correlating the amount or frequency of its donations with the number of subsidized prescriptions for its products; and

g. The manufacturer does not earmark its donations for narrow disease categories (or for use of a specific drug) which, for example, are defined by reference to specific symptoms, severity of symptoms, or method of administration of drugs. Manufacturers should limit their earmarked donations to PAPs that define categories in accordance with widely recognized clinical standards and in a manner that covers a broad spectrum of available products.

68. In 2014, OIG issued a Supplemental Bulletin on pharmaceutical companies' "indirect remuneration to patients" through "contributions to PAP[s]" operated by independent charities.[12] In that Supplemental Bulletin OIG reiterated that "[i]f a donation is made to a PAP to induce the PAP to…arrange for the purchase of the donor's federally reimbursable items, the [federal Anti-Kickback] statute could be violated."

69. In the Supplemental Bulletin, OIG also emphasized that independent charities cannot "give a donor any information that would enable a donor to correlate the amount or frequency of its donations with the number of aid recipients who use its products or services or the volume of those products supported by the PAP." Similarly, the OIG noted that "actions by donors to correlate their funding of PAPs with support for their own products . . . may be indicative of a donor's intent to channel its financial support to copayments of its own products, which would implicate the anti-kickback statute." Therefore, the Anti-Kickback Statute prohibits drug manufacturers from using a PAP as a mere conduit to do that which they cannot do themselves – provide kickbacks to their patients.

70. The federal Anti-Kickback statute is supplemented by a number of state laws that prohibit the same type of conduct. Many of these state statutes prohibit causing the submission of claims tainted by kickbacks to insurers even outside of the context of a governmental health insurance program.

[12] Supplemental Special Advisory Bulletin: Independent Charity Patient Assistance Programs, 79 Fed. Reg. 31120-31123 (May 30, 2014).

71. In addition to the Anti-Kickback statute, the False Claims Act (31 U.S.C. § 3729) prohibits knowingly causing the submission of fraudulent claims for payment to a federal health program like Medicare.

72. Pursuant to 31 U.S.C. § 3729(a), claims for reimbursement to the Medicare program that result in violation of the federal Anti-Kickback statute constitute *per se* violations of the False Claims Act.

UNITED THERAPEUTICS' FRAUDULENT SCHEME

73. The annual cost of UT's PAH drugs is extremely high, ranging from $46,000 to $170,000 per year. The cost-sharing obligations associated with those high prices make UT's drugs cost prohibitive for most patients.

74. Humana's benefit plans require that members pay cost-sharing obligations for drugs before Humana will reimburse for those prescriptions.

75. UT knew its "commercial success is tied to [] third-party payers."[13] The only way for UT to realize the full, annual cost of its drugs as revenue is if insured patients stay on their drugs and those patients satisfy their cost-sharing obligations and thus trigger coverage from their insurer. Thus, any limitation of coverage or reimbursement by those insurers could lead patients to "choose competing products that are approved for reimbursement or provide lower out-of-pocket costs."[14]

76. UT could have simply lowered the price of its drugs to make them more affordable while still delivering a healthy profit. Instead, it illegally subverted the cost-

[13] United Therapeutics Corporation, Annual Report, p. 43 (Form 10-K) (Dec. 31, 2013).
[14] *Id.*

sharing obligations discussed above, funneling millions of dollars to patients through CVC in the form of sham charitable donations. On information and belief, UT used ASSIST to further its fraudulent scheme to utilize foundational assistance programs as a conduit to provide kickbacks to Humana members.

United Therapeutics Illegally Uses CVC to Funnel Money to Patients

77. UT purported to donate many millions of dollars annually to CVC between 2010 and 2017. In reality, UT covertly used CVC as a conduit to funnel money to Medicare beneficiaries taking UT's PAH drugs, including individuals enrolled in Humana's Medicare plans. These payments eliminated the cost-sharing obligations associated with UT's PAH drugs under Humana Medicare plans and allowed UT to sell its PAH drugs at wildly inflated prices.

78. UT accomplished its scheme through illegal information sharing of a nature prohibited by the federal Anti-Kickback Statute.

79. Beginning as late as 2010, UT routinely obtained data from CVC detailing how many UT patients CVC had assisted, how much CVC had spent on those patients, and how much CVC expected to spend on those patients in the future.

80. On information and belief, UT received such information from CVC through funding requests, telephone calls, and written reports.

81. UT then used that information to budget for future payments to CVC on a drug-specific basis and to confirm that its contributions to CVC were sufficient to cover the cost-sharing obligations of patients taking UT's PAH drugs.

82. UT made certain that its payments to CVC were used exclusively to ensure that patients filling prescriptions for its PAH drugs would not bear any part of the cost of those drugs. Put another way, UT secretly funded the routine waiver of Humana members' cost-sharing obligations.

83. CVC obliged, using the money it received from UT to pay patients' cost-sharing obligations for UT's PAH drugs, thereby keeping patients and doctors from balking at the extraordinarily high cost of UT's PAH drugs.

84. CVC functioned as a payor of last resort. When a patient receives drugs from a pharmacy any applicable cost share is owed to the pharmacy. Accordingly, CVC would distribute funds directly to pharmacies after Humana had adjudicated a claim for payment for a UT drug. The pharmacy would take the explanation of benefits received from Humana and send it to CVC, thereby informing CVC of what the patient's cost share obligation was. CVC would then transfer money—UT's money—to cover the patient's balance.

85. On information and belief, CVC utilized other means of distributing UT's funds to patients. These include paying patients directly by check or providing patients with a reloadable debit card. Under these scenarios the patient would be responsible for paying a pharmacy directly using funds provided by CVC.

86. When a patient received a UT drug requiring administration by a medical provider—such as an itnravenous infusion of Remodulin—patients owe their balance to that provider. In this scenario, the payment options described above functioned the same, only with the provider in place of the pharmacy.

87. Using the above methods, UT thus effectively eliminated economic constraints on the prices that it could charge for its drugs. By underwriting the cost of its PAH drugs, UT rendered its drugs "free" to patients (or close to it), knowing that the resulting profits from higher drug sales at higher prices would dwarf the amounts it paid to patients through CVC.

88. The Federal Government has been clear that drug manufacturers cannot legally pay patient cost-sharing obligations, whether directly or through a third party. To that end, the federal Anti-Kickback statute prohibits information sharing between pharmaceutical manufacturers and patient charities (as discussed above). UT's coordination with CVC thus violated federal law.

89. On information and belief, UT paid CVC tens, if not hundreds, of millions of dollars annually to fund cost-sharing assistance programs in furtherance of the scheme described above.

90. To wit, in 2010 CVC reported $49,735,220 in donations.[15] By 2014 donations totaled $131,446,246.[16] CVC was not required to identify its donors, but its reliance on a select few was clear. In 2011 50% of CVC's donations came from a single source, dropping to 35% the following year.[17] By 2014 four donors contributed 91% of all donations.[18]

[15] Caring Voice Coalition, Public Inspection Report (Form 990) (2010).
[16] Caring Voice Coalition, Public Inspection Report (Form 990) (2014).
[17] Caring Voice Coalition, Financial Report (June 30, 2013).
[18] Caring Voice Coalition, Financial Report (June 30, 2014).

91. UT, for its part, never disclosed how much or to whom it donated money. It did, however, disclose how much its donations changed year-over-year. These disclosures, made pursuant of UT's obligations as a public company, made clear that UT's involvement with patient charities like CVC was worth millions of dollars. UT's donations were classified as "general and administrative" expenses.

92. In 2010 UT reported a year-on-year "increase of $5.3 million in grants to unaffiliated, not-for-profit organizations that provide therapy-related financial assistance and programs to patients suffering from PAH."[19]United Therapeutics Corporation, Annual Report, p. 62 (Form 10-K) (Dec. 31, 2010).

93. In 2012 UT reported a similar year-on-year "$6.3 million increase, principally in grants to non-affiliated, not-for-profit organizations that provide financial assistance to patients with PAH."[20]

94. Again in 2013 UT reported a year-on-year increase of $9.2 million "in grants to non-affiliated, non-profit organizations that provide financial assistance to patients with PAH due to the growth of patients using our products, in particular, Adcirca."[21]

[19] 2010 Form 10-K, *supra* note 11 at 62.
[20] 2012 Form 10-K, *supra* note 11 at 75.
[21] 2013 Form 10-K, *supra* note 16 at 73.

95. The trend continued in 2014, with UT reported a year-on-year, "$8.7 million increase in grants to nonaffiliated, non-profit organizations that provide financial assistance to patients with PAH."[22]

96. UT did decrease its donations from 2014 to 2015 by $12.7 million but made up for it with a $20 million annual increase the following year.[23] The Department of Justice served a subpoena on UT regarding its charity relationships that year.

97. Just before the DOJ served its subpoena, UT made yet another astonishingly high, $37 million lump sum donation to:

> [A] non-affiliated, non-profit organization that provides financial assistance to patients with PAH. Donations to the same organization in 2016 totaled $37.0 million, all of which were paid during the first quarter of this year. Donations to the same organization in 2015 were $17.0 million, all of which were paid in the second quarter of 2015. The donations made during the first quarter of 2016 and the second quarter of 2015 represent the full extent of our funding to this organization for these two years.[24]

The recipient of these funds was CVC.

98. 501(c)(3) entities like CVC are not required to disclose their donors, but it is common for publicly-filed Form 990 disclosures to include an anonymized the Schedule of Contributors (Schedule B) showing individual donation amounts. CVC used a fiscal year that ran from July 1 to June 30, so its 2015 Form 990 spanned July 1, 2015

[22] 2012 Form 10-K, *supra* note 11 at 72.
[23] United Therapeutics Corporation, Annual Report, p. 58 (Form 10-K) (Dec. 31, 2016).
[24] United Therapeutics Corporation, Quarterly Report, p. 27 (Form 10-Q) (Mar. 31, 2014).

to June 30, 2016. CVC's 2015 Form 990 disclosed that the second largest donor that year had donated $37 million[25]—*precisely the amount that UT disclosed*.

99. As the government's investigations into both UT and CVC intensified in 2017, UT's donations dropped by $32 million. United Therapeutics Corporation, Annual Report, p. 63 (Form 10-K) (Dec. 31, 2017).

100. On information and belief, the overt acts UT undertook to perpetuate this unlawful scheme include: (a) routinely obtaining information from CVC regarding patients receiving UT's PAH Drugs who CVC was assisting, including Humana members, along with the amounts necessary to eliminate their relevant cost-sharing obligations; (b) calculating payments to CVC to specifically cover, and which correspond to, the financial needs of patients taking UT's PAH Drugs, including Humana members; (c) confirming that the revenue generated by UT's funneling of funds through CVC would far exceed the amount of payments UT made to CVC; (d) making massive payments to CVC to advance its unlawful scheme; and (e) ensuring that those payments were directed to satisfy the cost-sharing obligations of patients receiving UT's PAH Drugs, including Humana members.

101. On information and belief, the overt acts CVC undertook to perpetuate this unlawful scheme include: (a) routinely providing UT with information describing the patients prescribed UT's PAH Drugs who were receiving assistance from CVC, including Humana members, and how much money was necessary to eliminate their relevant cost-

[25] Caring Voice Coalition, Public Inspection Report (Form 990) (2010).

sharing obligations (so that UT could calculate and send massive, corresponding payments to CVC); and (b) routing the payments CVC received from UT directly to patients receiving UT's PAH Drugs, including Humana members, in order to eliminate their relevant cost-sharing obligations.

102. The concerted actions of UT and CVC, and the unlawful acts they perpetrated, directly and proximately caused significant damages to Humana in the form of payments Humana made for UT's PAH Drugs that Humana would not have made, at prices that were far higher than UT could otherwise have charged for the drugs.

103. Because claims resulting from the arrangement described above were tainted by illegal kickbacks, they were not payable under Humana's Medicare plans as a matter of federal law. Humana would not have paid these claims had it known of UT's illegal conduct.

Humana's Coverage of UT Drugs

104. As described above, Humana's Evidence of Coverage documents require a member to pay their cost-sharing obligations, and states that payments made by third parties, except in limited circumstances, will not count towards a members' out-of-pocket expenses.

105. For example, Exhibit A, an EOC for a 2011 Humana Part D plan, clearly states that it is the member responsibility to pay their share toward drugs they receive. Ex. B at 67. It further states that under the plan "[i]t matters who pays" for a member's out-of-pocket costs. "If you make these payments **yourself**, they are included in your out-

of-pocket costs." *Id.* at 49. (Bold in original.) In other words, a member has to pay their share *themselves* for the payments to count toward their plan's coverage stage.

106. The Part D EOC also allows for payments to be made on a member's behalf by select groups. *Id.* at 49. Crucially, there is no allowance for financially interested actors. In fact, the Part D EOC states that when members get drugs through manufacturer-sponsored patient assistance programs, Humana "will not pay for any of these drug costs." *Id.* at 72.

107. Additionally, an Evidence of Coverage for a 2014 Humana Gold Choice Medicare Advantage plan is attached as Exhibit B.

108. Exhibit B contains the same general provisions as Exhibit A. *See* Ex. B at 111, 122. It further states that medical benefits are only available to members if their "Medicare-covered services [are] provided according to coverage guidelines established by Medicare." *Id*. at 49.

109. UT understood that Medicare payors like Humana would not pay claims if they understood that UT had taken the foregoing actions to eliminate member cost-sharing obligations.

110. A primary purpose of UT's conspiracy with CVC thus was to conceal its illegal payments from Medicare payors, including Humana, with a false veneer of charity.

United Therapeutics Induces Prescriptions of PAH Drugs with its ASSIST Program

111. Doctors generally will not prescribe drugs that they know their patients cannot afford. Similarly, patients will not—indeed, *cannot*—buy drugs for which they are

unable to pay. Indeed, a recent survey found that 27% of respondent patients had at one time declined to fill a prescription due to cost.[26]

112. UT well understood that due to the cost-sharing obligations discussed above, it could not sell its PAH drugs to an appreciable number of patients at the high prices it set for the drugs. The ultimate objective of the scheme described above was to induce sales of UT's drugs at inflated prices by removing the impediment posed by cost-sharing obligations.

113. UT further understood that, if doctors and patients believed that patients would bear the cost of UT's PAH drugs, doctors would not prescribe them, and patients would not purchase them. UT therefore erected a system by which it could funnel patients to the very "independent" patient assistance charities that UT was funding. UT accomplished this using its Access Solutions and Support Team (ASSIST).

114. UT advertised ASSIST to doctors as a "centralized referral service" to facilitate treatment with UT's PAH drugs. *See, e.g.,* Exhibit C (re Orenitram) and Exhibit D (re Adcirca). Doctors enrolled their patients by submitting referral forms created by UT. UT would then use the information on the forms to "contact [patients] to discuss its various available services," "determine [patients'] initial and continuing eligibility for the assistance program," and "administer the assistance program(s)." *Id.*

[26] Patient Engagement HIT, *Healthcare Costs Dampen Patient Engagement Despite Satisfaction* (May 19, 2016), available at https://patientengagementhit.com/news/healthcare-costs-dampen-patient-engagement-despite-satisfaction.

115. For Medicare patients, UT's ASSIST "worked with eligible patients and referred them for charitable assistance" to CVC.[27] ASSIST would then work with CVC to ensure that these patients received the funds "donated" by UT. UT thus ensured that patients would not be deterred by the high price of its PAH drugs, and induced patients to purchase those drugs, by routing them to CVC or another charity.

116. In this regard, ASSIST provided UT with insight on the precise number of patients and claims receiving financial assistance from the "charity" and thus provided UT with additional data from which to correlate its charitable funding.

117. ASSIST also served to assure doctors that their patients would not bear the high costs of UT's PAH drugs. This induced doctors to prescribe UT's drugs, which they would not have prescribed in the absence of "charitable" funding.

118. UT understood that sales of its PAH drugs depended on reimbursement by Medicare payors like Humana. UT therefore further used ASSIST to facilitate the submission and payment of claims for UT's PAH drugs tainted by the scheme described above.

119. Indeed, UT mandated ASSIST's involvement in every patient's care. A UT drug-specific referral form was required for a patient to get started on any UT drug, and those referral forms put ASSIST's role at the fore. *See* Exhibit C (re Orenitram) and

[27] *See* Memorandum of Law in Support of Defendant United Therapeutics Corporation's Motion to Transfer Venue to the U.S. District Court for the Southern District of Florida at 3, *MSP Recovery Claims, Series LLC et al. v. Caring Voice Coalition, Inc. et al.*, Case No. 1:20-cv-11418 (D. Mass. Dec. 29, 2020).

Exhibit D (re Adcirca). On information and belief, UT drugs would not be available unless a patient was connected with ASSIST.

120. As part of its role, ASSIST regularly contacted insurers such as Humana, to perform "benefit investigations" related to UT patients. The purpose of these benefits investigations was "to help research and verify whether [a] patient's prescribed medication is covered, their estimated co-payments, if prior authorization is required, and which Specialty Pharmacy the health plan prefers."[28]

121. UT also regularly contacted payors through ASSIST to facilitate the submission of claims for its PAH drugs, and thereby obtained the details of the contractual provisions at issue in this litigation.

122. ASSIST also provided a suite of other services to doctors designed to facilitate the submission of claims, and appeals of denied claims, for UT's PAH drugs.

123. UT thus used ASSIST to ensure that Medicare payors like Humana paid the tainted claims generated by its fraudulent scheme and was able to use it to gather metrics on the utilization of foundational assistance through its fraudulent scheme.

United Therapeutics Reaps Astronomical Profits from its Scheme

124. Not coincidentally, UT's profits exploded around the time that it commenced its scheme.

125. UT achieved this result in part by significantly increasing the price of Remodulin shortly after it began coordinating with CVC. Because UT's scheme rendered

[28] Coverage and Reimbursement Assistance for Remodulin, ASSIST United Therapeutics, https://www.utassist.com/hcp/coverage-reimbursement/remodulin, (last visited Dec. 8, 2022).

the price of the drug irrelevant to patients and physicians, this increase in Remodulin's price did not have any negative impact on sales. Indeed, sales of Remodulin only *increased*.

126. As a direct result of the scheme described above, UT similarly increased the number of patients using its other PAH drugs without lowering the exorbitant prices for its drugs, and thus the corresponding sales of those drugs.

127. Within a year of starting its conspiracy with CVC, UT's profit margin went from negative 17% to positive 17%, topping out in 2012 with a profit margin 34.5% in 2012. Nearly all of these profits came from UT's PAH drugs.

128. Between 2009 and 2014, UT also increased its yearly revenue from around $350 million to $1.2 billion in 2014, more than tripling its revenue. These astronomical profits—based on the sale of a handful of drugs used to treat a rare condition—were only possible due to the scheme described above.

129. These windfall profits lined the pockets of UT's executives. During the scheme, the New York Times ranked UT's CEO among the ten most highly compensated executives in the United States. In 2013 alone, she received $38.2 million in compensation from UT.[29]

[29] Steven Overly, *United Therapeutics Slashes Pay for CEO Martine Rothblatt After Shareholder Vote*, Washington Post (Dec. 17, 2014), https://www.washingtonpost.com/business/capitalbusiness/united-therapeutics-slashes-pay-for-ceo-martine-rothblatt-after-shareholder-vote/2014/12/17/383992a8-861e-11e4-a702-fa31ff4ae98e_story.html.

130. CVC likewise enjoyed significant financial benefits from the scheme. CVC retained a substantial portion of UT's donations (on information and belief, roughly 9%) as "administrative fees" and the salaries of its executives soared throughout this period.

131. These profits came at the expense of healthcare payors like Humana, who ultimately bore the tremendous cost of UT's drugs.

United Therapeutic's False Representations and Certifications of Compliance with Federal Law

132. To perpetrate its scheme UT made and caused to be made false representations and certifications to Humana of compliance with state and federal law, including laws related to bribery, kickbacks, and false claims.

133. Medicare Plan Sponsors must comply with federal laws and regulations designed to prevent fraud, waste, and abuse, including, but not limited to, applicable provisions of Federal criminal law, the False Claims Act, and the Anti-Kickback Statute. Any "downstream" or "related" entities that Medicare Plan Sponsors subcontract with (including pharmacies dispensing drugs and manufacturers selling drugs) must also comply with these, and any other, contractual obligations of the Plan and with all applicable federal laws, regulations, and CMS instructions.

134. Drug manufacturers that elect to participate in Medicare therefore certify their compliance with the Anti-Kickback Statute.

135. Humana agreed to cover and pay for UT's PAH drugs in reliance on UT's certification of compliance with applicable federal laws. Humana would not have done so had it understood this certification to be false.

136. UT reiterated and amplified its false certifications of compliance with federal law in a 2013 rebate agreement with Humana. In particular, UT agreed that it "has and will take under consideration" the OIG Compliance Program Guidance for Pharmaceutical Manufacturers and that it would "comply with all applicable federal and state laws and regulations, CMS guidance, and Part D Rules . . .includ[ing]the Federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b)."

137. UT further caused to be made false certifications of compliance with federal law in connection with individual claims.

138. When a pharmacy dispenses drugs and submits a claim, the pharmacy generates an electronic record of the claim, called a Prescription Drug Event ("PDE"). After dispensing the drug, the pharmacy receives reimbursement from Humana for a portion of the drug cost not paid by the member at the point of sale.

139. CMS regulations require Medicare Plan Sponsors and related "downstream" entities that generate and submit PDE claims data to certify that such data is true, accurate, and complete and that the PDE data is the basis for obtaining federal reimbursement for the healthcare products or services reflected herein. Congress has determined that any Medicare claim "that includes items or services resulting from a violation of [the AKS] constitutes a false or fraudulent claim for purposes of the False Claims Act."

140. UT made, and deliberately caused pharmacies to make, such certifications and therefore misrepresented to Humana that it was complying with federal law in connection with each claim at issue in this litigation.

United Therapeutics Pays the Federal Government $210 Million to Resolve Allegations that it Used the Caring Voice Coalition to Pay Illegal Kickbacks

141. For years, UT acted in secret, coordinating its conduct with CVC covertly.

142. But the DOJ launched an investigation into UT's relationship with CVC that brought UT's scheme to light. On December 20, 2017, the DOJ announced that UT had agreed to pay $210 million to resolve allegations that it paid kickbacks through CVC.

143. In its settlement agreement with UT, DOJ made clear that "[w]hen a Medicare beneficiary obtains a prescription drug covered by Medicare Part B or Part D, the beneficiary may be required to make a payment, which may take the form of a 'copayment,' 'coinsurance,' or 'deductible' (collectively "copays"). The Anti-Kickback statute, 42 U.S.C. § 1320a-7b, prohibits pharmaceutical companies from paying remuneration to induce Medicare beneficiaries to purchase, or their physicians to prescribe, drugs that are reimbursed by Medicare."

144. According to the DOJ, UT used CVC as a conduit to pay the cost-sharing obligations of thousands of Medicare patients taking UT's PAH drugs, including Adcirca, Orenitram, Remodulin, or Tyvaso. The government alleged that by paying those cost-sharing obligations, UT "eliminate[d] price sensitivity of patients purchasing or physicians prescribing the Subject Drugs, and . . . induce[d] those patients' purchases of the [drugs at issue]."[30]

[30] Settlement Agreement with United Therapeutics Corporation, U.S. Dep't of Justice, (Dec. 19, 2017), https://www.justice.gov/usao-ma/press-release/file/1019336/download

145. The DOJ found that UT did so by "routinely obtain[ing] data from the foundation detailing how much the foundation had spent for patients on each [of the drugs at issue,] and that this data was used by UT to decide how much to donate to the foundation" to cover the cost-sharing obligations of patients taking UT's drugs, and only UT's drugs. [31]

146. Further, UT used its ASSIST program or some other mechanism to steer Medicare patients toward the CVC and other patient assistance foundations. As the DOJ recited, "UT had a policy of not permitting Medicare patients to participate in its free drug program. . . . Instead, in order to generate revenue from Medicare and to induce purchases of the Subject Drugs, UT referred Medicare patients prescribed the Subject Drugs to CVC."[32]

147. In announcing its settlement with UT, the DOJ explained that UT "used a third party to do exactly what it knew it could not lawfully do itself." The DOJ found that "UT's payments to the [CVC] were not charity for PAH patients generally, but rather were a way to funnel money to patients taking UT drugs." This conduct violated the federal Anti-Kickback Statute and False Claims Act, which combat "schemes like [UT's] that leave Medicare holding the bag for the costs of expensive drugs."

[31] *Id.*
[32] *Id.*

148. The DOJ further emphasized that UT's conduct undermined the Medicare program's co-pay structure, which Congress created as a safeguard against inflated drug prices.

149. In conjunction with the settlement, UT entered into an extensive Corporate Integrity Agreement with the federal government.[33] The Agreement required UT to cease its unlawful coordination with CVC, and to take a variety of prophylactic steps to prevent it from engaging in further fraudulent activity.

150. UT was not the only manufacturer of PAH drugs the DOJ found to have violated the law. In December of 2018, the DOJ announced that Actelion Pharmaceuticals US, Inc. had agreed to pay $360 million "to resolve claims that it illegally used [CVC] as a conduit to pay the copays of thousands of Medicare patients taking Actelion's pulmonary arterial hypertension drugs." The DOJ found that Actelion likewise "routinely obtained data from the foundation detailing how much the foundation had spent for patients on each Subject Drug; it then used this information to decide how much to donate to the foundation and to confirm that its contributions were sufficient to cover the copays of only patients taking the Subject Drugs." [34]

[33] Corporate Integrity Agreement Between the Office of Inspector General of the Department of Health and Human Services and United Therapeutics Corporation, Office of Inspector General (Dec. 18, 2017), https://oig.hhs.gov/fraud/cia/agreements/United_Therapeutics_Corporation_12182017.pdf.

[34] Department of Justice, Drug Maker Actelion Agrees to Pay $360 Million to Resolve False Claims Act Liability for Paying Kickbacks, U.S. Dep't of Justice (Dec. 6, 2018), https://www.justice.gov/opa/pr/drug-maker-actelion-agrees-pay-360-million-resolve-false-claims-act-liability-paying.

151. Indeed, Humana's own investigation revealed members who simultaneously took UT and Actelion drugs and received CVC assistance for both.

OIG Rescinds its Advisory Opinion Concerning the Caring Voice Coalition

152. OIG's 2006 advisory opinion setting out guidelines for relationships between patient charities and pharmaceutical manufacturers came at the request of CVC.

153. On November 28, 2017 OIG rescinded its 2006 Advisory Opinion[35] because it learned (as a result of the DOJ's investigation) that CVC failed to comply with certain factual certifications made to OIG when seeking the opinion and that those certifications were material to OIG's conclusion that the arrangement had a low risk of violating the Anti-Kickback statute.

154. Specifically, OIG found that CVC provided patient-specific data to one or more donors that would enable the donors to correlate the amount and frequency of their donations with the number of subsidized prescriptions or orders for their products.

155. Likewise OIG found that CVC allowed donors to directly or indirectly influence the identification or delineation of CVC's disease categories.

156. OIG concluded that CVC's failure to comply with those certifications materially increased the risk that CVC served as a conduit for financial assistance from a pharmaceutical manufacturer donor to a patient, and thus increased the risk that the

[35] Rescission of Advisory Opinion 06-04, Office of Inspector General (Dec. 28, 2017), https://oig.hhs.gov/fraud/docs/advisoryopinions/2017/AdvOpnRescission06-04.pdf

patients who sought assistance from CVC would be steered to drugs that the manufacturer donor sold.

157. The OIG's decision caused CVC to cancel its assistance operations effective December 31, 2017.[36] While CVC was wound down, its management set up a new entity to succeed CVC known as the Adira Foundation. CVC then transferred $4.2 million in cash along with its other assets to Adira.[37] On information and belief, this transfer included CVC's patient assistance data and the software needed to access it.

158. On further information and belief, as CVC closed UT shifted its donations to the Patient Access Network Foundation ("PANF"), another patient assistance charity. PANF's pulmonary hypertension fund opened on January 2, 2018.[38]

159. Exhibit E is a representative sample of claims affected by UT's scheme which illustrates the sudden shift of one Humana member from CVC assistance to PANF assistance.

Humana Was Damaged by United Therapeutic's Payment of Humana Member Cost-Sharing Obligations

160. Humana has paid hundreds of millions of dollars for UT's drugs since the scheme's inception in 2010 and, on information and belief, a significant portion of those prescriptions were not reimbursable because they were tainted by UT's illegal kickbacks.

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[36] Greg Smiley, A Decision on 2018 Financial Assistance, Caring Voice Coalition (Jan. 4, 2018), https://web.archive.org/web/20180109020321/http://www.caringvoice.org/decision-2018-financial-assistance/ (last accessed Dec. 8, 2022).
[37] Caring Voice Coalition, Report of Independent Accountants (Sept. 23, 2021).
[38] *New pulmonary hypertension fund opens*, Patient Access Network Foundation (Jan. 2, 2018), https://www.panfoundation.org/patient-access-network-foundation-opens-new-pulmonary-hypertension-patient-assistance-fund/.

161. Humana's own investigation has confirmed that UT's scheme caused Humana to pay on tainted claims. Exhibit E is a sample of 16 Humana members on whose behalf Humana paid $7,400,927 for UT drugs. These members had a collective cost-share obligation of $395,687, meaning UT—via CVC and PANF—received $18.70 for every $1 of its "donations" that went to Humana members.

162. Humana would not have paid *any* of the claims listed in Exhibit E had it known about UT's fraudulent scheme. Some exemplary individual claims from Exhibit E follow.

163. Member 2 identified CVC as providing cost share assistance for their Remodulin prescriptions from 2012 through 2017. Member 2 received a Remodulin treatment on July 17, 2022 for which Humana was billed $13,324.14. Pursuant to Member 2's plan they owed cost share worth $333.45, but UT paid this amount via CVC, causing Humana to pay the remaining $12,990.69.

164. Member 4 identified CVC as providing cost share assistance for their Adcirca prescriptions from 2011 to 2018. Member 2 received an Adcirca prescription on July 27, 2012 for which Humana was billed $1,490.19. Pursuant to Member 4's plan they owed cost share worth $74.51, but UT paid this amount via CVC, causing Humana to pay the remaining $1,415.68.

165. Member 10 identified CVC as providing cost share assistance for their Orenitram prescriptions in 2014. Member 10 received an Orenitram prescription on June 26, 2014 for which Humana was billed $7,795.13. Pursuant to Member 10's plan they

owed cost share worth $389.76, but UT paid this amount via CVC, causing Humana to pay the remaining $7,405.37.

166. Member 14 identified CVC as providing cost share assistance for their Tyvaso and Adcirca prescriptions from 2011 to 2016. Member 14 received a Tyvaso treatment on May 17, 2011 for which Humana was billed $12,620.16. Pursuant to Member 14's plan they owed cost share worth $900.67, but UT paid this amount via CVC, causing Humana to pay the remaining $11,719.49. Humana would not have paid this claim had it known of UT's fraudulent scheme.

167. Humana is entitled damages in the amount of all reimbursements paid where UT, through CVC or another third-party, paid Humana member cost-sharing amounts.

168. Because of the secretive nature of UT's arrangement with CVC, which was not made public until December of 2017, Humana does not yet know the full scope of the damage caused as a result of UT's illegal conduct. The information necessary to make that determination is uniquely within the possession of UT and its co-conspirators.

TOLLING

169. To the extent any limitations periods might apply to claims Humana has against UT, those limitations periods have not run because UT has been engaged in continuing, repetitive, tortious conduct, causing additional and ongoing injury to Humana. Because UT's repetitive tortious conduct has not ceased, no limitations periods on Humana's claims have started to run.

170. Moreover, even if one or more limitations periods could apply, they would be tolled by virtue of the discovery rule. UT concealed the central components of its scheme, making it difficult to discover. Indeed, the very purpose of UT using charitable foundations like CVC as a conduit through which to pay the cost-sharing obligations of patients taking UT's PAH Drugs was to conceal the fact that UT was supplying the payments. Humana only learned of this conduct on December 20, 2017 when DOJ announced its settlement with UT.

171. In addition, Humana's claims against UT have been expressly tolled by agreement of the parties since August 26, 2020.

COUNT I
FRAUDULENT CONCEALMENT

172. Humana incorporates by reference the foregoing paragraphs as if fully set forth herein and further alleges as follows.

173. UT knew that payors including Humana ultimately pay for UT's PAH drugs.

174. UT had superior knowledge of facts unavailable to Humana that UT knew to be material to Humana's decision to reimburse for UT's PAH drugs. Specifically, UT had knowledge of the following facts:

175. UT illegally steered patients to CVC.

176. UT illegally received information from CVC regarding CVC's payments to cover the cost-sharing obligations of UT's PAH drugs;

177. UT illegally used this information to calibrate its donations to CVC to cover only the cost-sharing obligations of its PAH drugs;

178. UT and CVC illegally coordinated to ensure that UT's donations were routed to patients receiving UT's PAH drugs;

179. As a result, CVC was not acting as an independent, *bona fide* charity, but rather as an illegal conduit for UT to systematically eliminate the cost-sharing obligations of patients receiving UT's PAH drugs;

180. The effect of UT's scheme was effectively UT's covert waiver of the cost-sharing of most or all patients' receiving UT's PAH drugs; and

181. By eliminating virtually all of the cost-sharing obligations of patients receiving UT's PAH drugs through a combination of its unlawful relationship with CVC and its copay card program, UT was able to vastly inflate the price of its PAH drugs.

182. UT knew that Humana lacked knowledge of the above facts, and that the above facts were material to Humana's decision to reimburse claims for UT's PAH drugs, and that Humana would not reimburse for UT treatment if it learned of any of the above facts. Indeed, the above facts rendered claims for UT's PAH drugs submitted to Humana's Medicare plans not payable under Federal law.

183. UT further knew that providers submitting claims to Humana for UT's PAH drugs would affirmatively certify that the claims were not tainted by illegal kickbacks. UT knew that its relationship with CVC violated the federal AKS, rendering those certifications false. UT further knew that Humana lacked knowledge of the falsity

of these certifications, and that Humana would rely on them in reimbursing for UT's PAH drugs.

184. UT's superior knowledge related to Humana's reimbursements for UT's PAH drugs, payments that UT closely monitored, and upon which UT's business depended, gave rise to a duty on UT's part to disclose the facts discussed above. UT's active concealment of its illegal conduct with the intent to deceive Humana also independently gave rise to a duty to disclose the facts discussed above.

185. UT did not disclose those material facts. Instead, UT took active steps to hide them, working to disguise its illegal payments to patients as "charitable donations."

186. UT regularly contacted Humana, through its ASSIST program, in the course of performing "benefits investigations." UT never disclosed that the purpose for which it sought the information at issue was to enable UT to illegally eliminate the cost-sharing obligations of Humana members. Nor did UT disclose any of the other material facts discussed above.

187. In addition, UT entered into a rebate agreement with Humana, in which it certified that with respect to the scope of that agreement, that it shall "comply with all applicable federal and state laws and regulations, CMS guidance, and Part D Rules . . . [including], without limitation, the Federal Anti-Kickback Statute.

188. In entering this agreement, UT made partial statements to Humana regarding its compliance with applicable federal law, such as the AKS, giving rise to a duty to disclose the extent of its fraudulent scheme.

189. UT's decision to seek reimbursement for its drugs under Medicare Part D necessitated that UT agree to comply with federal law such as the AKS.

190. UT knew its conduct to be illegal, and that by concealing its scheme described above, it would deceived Humana into reimbursing claims for UT's PAH drugs that Humana would not otherwise pay.

191. Humana reasonably believed that UT and CVC were not engaged in a an illegal kickback scheme, and that the claims it received for UT's PAH drugs were not tainted by illegal kickbacks, and reasonably relied on those beliefs in paying claims for UT's PAH drugs.

192. As a result of UT's fraudulent concealment, Humana was damaged by paying hundreds of millions of dollars on claims for UT's PAH drugs that should not have been paid.

COUNT II
FRAUD

193. Humana incorporates by reference the foregoing paragraphs as if fully set forth herein and further alleges as follows.

194. UT made affirmative misrepresentations to entities and actors that submitted claims to Humana that it was complying with state and federal laws related to bribery, kickbacks, and false claims.

195. CMS regulations mandate that "downstream" entities comply with federal laws such as the AKS. Any Medicare claim that includes items or services that resulted

from a violation of the AKS is a false or fraudulent claim. UT's actions caused misrepresentations to be made to Humana alongside claims for payment for UT Drugs.

196. By making such certifications, and causing such certifications to be made, UT falsely certified, and deliberately caused pharmacies to falsely certify to Humana that the reported data was true, accurate, complete, and otherwise in compliance with federal laws, such as the False Claims act and the AKS.

197. But such certifications were false, as the claims were tainted by kickbacks, and thus in violation of the AKS.

198. Humana reasonably relies on these certifications to evaluate if it should continue to reimburse claims made resulting from that "channel" of downstream entities.

199. UT knew that these representations to be false, and both made them and caused them to be made in a deliberate effort to mislead Humana and other Medicare payors.

200. As a result of UT's false certifications, Humana was damaged by paying millions of dollars on claims for UT's PAH drugs that should not have been paid.

COUNT III
TORTIOUS INTERFERENCE WITH CONTRACT

201. Humana incorporates by reference the foregoing paragraphs as if fully set forth herein and further alleges as follows.

202. Humana members are each parties to Humana benefit plans, which are contracts between the members and Humana.

203. As is described in detail above, Humana's benefit plans require with limited exceptions that Humana *members*—not others paying on their behalf—pay the cost-sharing obligations set forth in the plans when obtaining drugs, including UT's PAH Drugs.

204. These plans forbid a pharmaceutical company from eliminating the cost-sharing obligations of Humana members by using a patient charity as a conduit.

205. For example, a sample benefit plan states that co-payment "is the amount *you* pay" each time that "you receive Covered Health Care Services." *See* Exhibit A.

206. UT knew that Humana members were parties to Humana benefit plans and that the plans required the members to pay cost-sharing obligations. Such requirements are standard features of commercial insurance plans, which stand as barriers between UT and its goals of maintaining and increasing the prices and utilization of its PAH drugs. Moreover, UT obtained the specific contractual terms at issue in this litigation by contacting Humana through its ASSIST program.

207. Despite that knowledge, UT intentionally interfered with those plan requirements by paying for and eliminating Humana members' cost-sharing obligations using CVC as a conduit to make the payments and conceal itself as the source of the funds.

208. UT's interference caused Humana members to breach their agreements with Humana when they failed to pay the cost-sharing obligations set forth in their insurance plans, but instead permitted UT to do so on their behalf.

209. UT's interference and procurement of those contractual breaches was wrongful and without justification, conducted solely to defeat the structure of Humana's managed care system and to benefit UT financially at Humana's expense.

210. The contractual breaches UT caused have directly and proximately caused significant damages to Humana in the form of payments Humana made for UT's PAH drugs, subsequent to and because of those breaches, which Humana should not have paid.

COUNT IV
AIDING AND ABETTING TORTIOUS CONDUCT

211. Humana incorporates by reference the foregoing paragraphs as if fully set forth herein and further alleges as follows.

212. UT agreed with CVC to commit the tortious acts described herein.

213. UT and CVC committed the foregoing wrongful acts in furtherance of their common scheme.

214. UT knew that its conduct and that of CVC constituted a breach of duty.

215. UT gave substantial assistance or encouragement to CVC to breach such duties.

216. UT's wrongful acts were a substantial factor in causing harm to Humana.

217. To the extent CVC was the primary tortfeasor with respect to any of the foregoing wrongful acts, UT is liable for aiding and abetting such wrongful acts.

COUNT V
VIOLATION OF CIVIL RICO, 18 U.S.C. § 1962(c)

218. Humana incorporates by reference the foregoing paragraphs as if fully set forth herein and further alleges as follows.

219. UT and CVC are "persons" within the meaning of 18 U.S.C. § 1961(3), who conducted the affairs of an enterprise through a pattern of racketeering activity in violation of 18 U.S.C. § 1962(c).

220. UT and CVC entered into an association-in-fact enterprise (the "Enterprise") within the meaning of 18 U.S.C. § 1961(4). The Enterprise was an ongoing organization that functioned as a continuing unit. The Enterprise was created and/or used as a tool to effectuate a pattern of racketeering activity. UT and CVC are both "persons" distinct from the Enterprise.

221. The enterprise operated continuously for at least seven years.

222. UT established the Enterprise with CVC to induce sales of its PAH drugs at inflated prices. UT and CVC played distinct and indispensable roles in the Enterprise. UT paid CVC many millions of dollars in sham "donations," publicized the availability of the resulting funds through its ASSIST program to induce sales of its PAH drugs and used its ASSIST program to facilitate the submission and payment of claims tainted by the scheme. CVC illegally provided information to UT to calculate its payments to CVC and channeled those payments directly to Medicare beneficiaries taking UT's drugs.

223. UT asserted control over the Enterprise by designing, organizing, and funding the sham charitable funds at CVC used to pay cost-sharing obligations of Medicare beneficiaries enrolled in Medicare plans administered by Humana.

224. UT has conducted and participated in the affairs of the Enterprise through a pattern of racketeering activity that includes acts indictable under 18 U.S.C. §§ 1341

(mail fraud), 1343 (wire fraud), 1952 (use of interstate facilities to conduct unlawful activity).

225. The Enterprise's predicate acts of racketeering include, but are not limited to, use of the wires and mails to defraud Humana into paying claims for UT's PAH drugs that Humana should not have paid in the following ways:

226. Transmitting or causing to be transmitted false certifications of compliance with federal law in connection with individual claims, including those listed in Exhibit C;

227. Coordinating payments from UT to CVC through illegal information sharing;

228. Transferring illegal payments from UT to CVC;

229. Advertising the availability of the illegal funding through UT's ASSIST program;

230. Referring Medicare beneficiaries to CVC for receipt of illegal funds, and disbursing those illegal funds;

231. Contacting Medicare payors (including Humana) to facilitate the payment of tainted claims for UT's PAH drugs; and

232. Inducing Humana to use the wires to transmit payment for claims tainted by the illegal scheme described above.

233. The effect of the Enterprise's racketeering activity was to subvert the cost-sharing obligations imposed by Medicare payors like Humana, to thereby induce sales of UT's PAH drugs at inflated prices, and to induce Medicare payors like Humana to pay claims by concealing UT's illegal payments.

234. The Enterprise deliberately targeted Medicare payors like Humana, not only by subverting the cost-sharing obligations of Medicare beneficiaries to induce prescriptions, but by facilitating the submission and payment of claims through the ASSIST program. The Enterprise thus directly and proximately caused Medicare payors (including Humana) to pay claims for UT's PAH drugs that they should not have paid.

235. The Enterprise damaged Humana through the foregoing conduct by causing it to pay claims for UT's PAH drugs that it should not have paid, and to pay wildly inflated prices for those drugs. These damages resulted directly and proximately from the Enterprise's racketeering activities described above.

COUNT VI
CONSPIRACY TO VIOLATE CIVIL RICO, 18 U.S.C. § 1962(d)

236. Humana incorporates the foregoing paragraphs as if fully set forth herein and further alleges as follows.

237. 18 U.S.C. § 1962(d) provides that it "shall be unlawful for any person to conspire to violate any of the provisions of subsection (a), (b) or (c) of this section."

238. UT violated 18 U.S.C. § 1962(d) by conspiring with CVC to violate 18 U.S.C. § 1962(c) in the manner described above. The object of this conspiracy has been and is to conduct or participate in, directly or indirectly, the conduct of the affairs of the Enterprise through a pattern of racketeering activity.

239. UT and CVC have engaged in numerous overt and predicate fraudulent racketeering acts in furtherance of the conspiracy.

240. The nature of the above acts, material misrepresentations, and omissions in furtherance of the conspiracy gives rise to an inference that UT and CVC not only agreed to the objective of an 18 U.S.C. § 1962(d) violation of RICO by conspiring to violate 18 U.S.C. § 1962(c), but they were aware that their ongoing acts have been and are part of an overall pattern of racketeering activity.

241. As a direct and proximate result of UT's overt acts and predicate acts in furtherance of violating 18 U.S.C. § 1962(d) by conspiring to violate 18 U.S.C. § 1962(c), Humana has been injured in its business and property as set forth more fully above.

242. The coordinated acts of UT and CVC damaged Humana by causing it to pay claims for UT's PAH drugs that it should not have paid, and to pay higher prices for those drugs than it should have paid.

COUNT VII
UNJUST ENRICHMENT

243. Humana incorporates by reference the foregoing paragraphs as if fully set forth herein and further alleges as follows.

244. Humana has conferred direct benefits on UT in the form of significant payments for UT's PAH Drugs utilized by Humana members.

245. UT has knowledge of those benefits, and in fact induced Humana to provide them through the conduct described above.

246. UT has voluntarily accepted and retained the payments it has received from Humana resulting from the scheme described above.

247. Under the circumstances of this case, it would be inequitable for UT to retain the payments and benefits it has received at Humana's expense.

248. The money UT has received from Humana belongs in equity and good conscience to Humana.

249. By virtue of the foregoing, Humana is entitled to recover the substantial amount of payments UT has improperly retained.

COUNT VIII
VIOLATION OF STATE DECEPTIVE TRADE PRACTICES LAWS

250. Humana incorporates by reference the foregoing paragraphs as if fully set forth herein and further alleges as follows.

251. By concealing its coordination and cooperation with the CVC to pay for and eliminate Humana member's cost-sharing obligations, UT deceived Humana into paying reimbursements for claims made by its members that it otherwise would not have.

252. UT's conduct affected not only Humana, but other Medicare payors and the federal government. The scheme defrauded taxpayers and burdened a critically important federal program upon which millions depend for healthcare.

253. UT's scheme also deceived and affected the drug-consuming public at large. As described above, skyrocketing drug prices present a significant harm to consumers, a burden on the United States healthcare system, and a substantial contributing factor to the overall rise in the cost of healthcare in the United States. UT's scheme subverted the primary restraint on the price of its PAH drugs, allowing UT to jack up its prices well beyond what the market would otherwise bear. The ill effects of

this scheme are ultimately borne not just by insurers like Humana, but drug and healthcare consumers in the Maryland and throughout the United States. In particular, any consumers whose doctors chose to prescribe UT's PAH drugs, but who (for whatever reason) failed to secure CVC funding, were forced to pay far more for UT's PAH drugs than they would have absent UT's fraud.

254. UT effectuated its scheme in part by directly targeting and deceiving patients and physicians through its ASSIST program.

255. UT's deceptive and inequitable conduct directly and proximately caused significant damages to Humana in the form of payments Humana made for UT's PAH drugs.

256. UT's fraudulent and deceptive business practices described herein violate the following state consumer fraud, consumer protection, and/or deceptive trade practices laws:

a. Ariz. Rev. Stat. Ann. § 44-1521, *et seq.* (Arizona);

b. Cal. Bus. & Prof. Code § 17200, *et seq.* (California);

c. Colo. Rev. Stat. § 6-1-101, *et seq.* (Colorado);

d. Conn. Gen. Stat. Ann. § 42-110g, *et seq.* (Connecticut);

e. Fla. Stat. § 501.201, *et seq.* (Florida);

f. 815 Ill. Comp. Stat. 505/1, *et seq.* (Illinois);

g. Mass. Gen. Laws ch. 93A, *et seq.*,

h. Mich. Comp. Laws § 445.901, *et seq.* (Michigan);

i. Minn. Stat. § 325F.68, *et seq.* (Minnesota);

j. Neb. Rev. Stat. § 59-1601, *et seq.* (Nebraska);

k. Nev. Rev. Stat. § 41.600, *et seq.* (Nevada)

l. N.J. Stat. Ann. § 56:8-2 (Pennsylvania);

m. N.H. Rev. Stat. Ann. § 358-A:1, *et seq.* (New Hampshire);

n. N.Y. Gen Bus. Law § 349, *et seq.* (New York);

o. N.C. Gen. Stat. § 75-1.1, *et seq.* (North Carolina);

p. Ohio Rev. Code Ann. § 1345.02, *et seq.* (Ohio);

q. Pa. Stat. Ann. tit. 73, § 201-1 (Pennsylvania); and

r. Wis. Stat. Ann. § 100.18 (Wisconsin).

257. Humana paid claims for UT's PAH drugs submitted from each of the foregoing states.

258. UT's conduct offends established public policy and the public interest, and is immoral, unethical, oppressive, unscrupulous, and substantially injurious to consumers.

259. Humana is therefore entitled to actual damages or damages for each deception that occurred, punitive damages, and attorney's fees.

COUNT VIX
VIOLATION OF STATE INSURANCE FRAUD LAWS

260. Humana incorporates by reference the foregoing paragraphs as if fully set forth herein and further alleges as follows.

261. Defendants have committed insurance fraud in violation of the laws of Illinois, Kentucky, Pennsylvania, New Jersey, and Tennessee; particularly the following laws:

a. Illinois, 720 Ill. Comp. Stat. 5/17-10.5;

b. Kentucky, Ky. Rev. Stat. § 304.47-010, *et seq.*;

c. Pennsylvania, 18 Pa. Cons. Stat. Ann. § 4117;

d. New Jersey, N.J. Stat. § 17:33A, *et seq.*; and

e. Tennessee, Tenn. Code. Ann. § 56-53-101, *et seq.*

262. UT knowingly presented, or caused to be presented, to Humana statements in support of claims for benefits for UT's PAH drugs that UT knew contained false and/or misleading information. UT knew and intended that, by engaging in its scheme to illegally subsidize copayments through phony charitable funds, misleading and/or false information would be submitted to Humana and other Medicare payors in connection with insurance claims. UT knew that the presentation of false claims to Humana was essential to its scheme.

263. The compliance certifications and other information submitted to Humana were material to Humana's decision to pay for UT PAH drug claims. Without them, Humana would not have paid the claims.

264. Humana's injuries were directly and proximately caused by the false or misleading statements that UT made to Humana, or caused to be submitted to Humana, as described above. By virtue of the foregoing, Humana is entitled to compensatory damages in an amount to be proven at trial, and such other relief that may be deemed just and proper.

PRAYER FOR RELIEF

WHEREFORE, Humana respectfully requests an award in its favor and granting the following relief:

265. An award of compensatory damages as requested herein;

266. Equitable relief as requested herein;

267. Injunctive relief as requested herein;

268. Treble damages under 18 U.S.C. § 1964(c);

269. Costs of court;

270. Reasonable attorney fees;

271. Prejudgment and post-judgment interest; and

272. An award of any other relief in law or equity that the Court deems just and proper.

JURY DEMAND

Pursuant to Federal Rule of Civil Procedure 38(b), Plaintiff demands a trial by jury on all issues so triable.

Dated: December 13, 2022

Funk & Bolton, P.A.

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